JUL 3 1 2012

510(k) SUMMARY

As required by section 807.92(c)

Submitter:	ALSEAL
Contacts:	M. DELFORGE Jean-François VALPARC - ESPACE VALENTIN 6 C Rue De Franche-Comté 25048 BESANCON Cedex - France Phone : 00333.81.61.69.93
Preparation Date:	November 16, 2011
Trade Name:	HQS Introducer (Model 2064-HQS)
Common Name:	Catheter Introducer
Classification Name:	Catheter Introducer
Regulation Number:	870.1340
Product Code:	DYB
Legally Marketed Predicate Devices:	Gore Dryseal Sheath (K093791) Manufactured By W.L. Gore & Associates,Inc
Device Description:	The High Quality Sealing (HQS) Introducer comprises 4 elements, a radio-opaque introducer sheath equipped with a haemostasis valve, a radio-opaque dilator, a centering wire device and an extension line with 3 ways stopcock. The range of HQS introducer (18F, 20F, 22F, 24F, 26F) permits the insertion, preserving sealing, of large caliber tools, from 0F, up to the nominal size of the introducer sheath. The introducer and its adjustable valve are easily handled with one hand. The distal tip is designed to perform an efficient introduction of the HQS introducer with the dilator in the vessel. The centering device permits to introduce a guidewire through the valve and to keep a perfect sealing. The extension line is connected to the lateral port of the introducer for the injection during the procedure.
Intended Use:	HQS INTRODUCER (Model 2064-HQS) is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.

Bench/ Performance data	The following in-vitro testing was performed on the HQS Introducer (Model 2064-HQS) in accordance with ISO standards and/or internal procedures to assure reliable design and performance. In-vitro design verification testing data demonstrate that the device is in compliance with ISO 11070:1999 Sterile, single use intravascular catheter introducers and product labeling. 1. Tensile strength 2. Overpressure resistance 3. Suction resistance 4. Introducer useful dimensions (lengths, Inside and Outside diameters) 5. Dilator useful dimensions (lengths, Inside and Outside diameters) 6. Sealing of the valve 7. Operating mechanism resistance 8. Visual control (atraumatic surface) 9. Resistance to kinking 10. Dilator compatibility (introduction / withdrawal) 11. Extension line connection 12. Centering device compatibility 13. Introducer/dilator distal transition 14. Compatibility with vascular tools and guidewire 15. Radiodetectability test 16. Packaging resistance 17. Sterilization tests 18. Aging tests
Non-Clinical Tests:	Biocompatibility tests In accordance with ISO 10993-1:2009, the following biocompatibility tests were conducted on the HQS Introducer (Model 2064-HQS): • Cytotoxicity (ISO 10993-5:2009) • Sensitization (ISO 10993-10:2006) • Intracutaneous Toxicity (ISO 10993-10:2006) • Systemic Toxicity (ISO 10993-11:2006) • Pyrogenicity (ISO 10993-11:2006) • Hemocompatibility o Hemolysis (ASTM Guideline F756:2008) o Prothrombin Time (ISO 10993-4:2006)

	○ Coagulation UPTT (ISO 10993-4:2006) ○ Platelet (ISO 10993-4:2006) ○ Complement Activation (ISO 10993-4:2006) ○ Thrombogencity (ISO 10993-4:2006) Results for all biocompatibility testing demonstrate that the materials used meet the requirements of ISO 10993-1:2009.
Substantial equivalence:	HQS INTRODUCER is compared to predicate legally marketed device GORE DRYSEAL SHEATH (K093791). HQS INTRODUCER is substantially equivalent to its predicate devices in terms of intended use, function and technological characteristics. Any minor differences between these two devices do not raise new questions of safety and effectiveness. Performance data included within this submission demonstrates safety, effectiveness and substantial equivalence.
Conclusion:	The studies conducted on the HQS Introducer (Model 2064-HQS) demonstrate that the device is substantially equivalent to the predicate devices currently in commercial distribution. The proposed device meets the performance criteria of design verification as specified by ISO standards and test protocols. Any differences between the devices do not raise any significant issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 31 2012

ALSEAL
c/o Intertek Testing Services
Ms. Paula Wilkerson
2307 E. Aurora Rd. Unit B7
Twinsburg, OH 44087

Re: K113849
Trade/Device Name: HQS Introducer (Model 2064 - HQS)
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 2, 2012
Received: July 10, 2012

Dear Ms. Wilkerson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K113849

Device Name: HQS INTRODUCER (Models 2064-HQS)

Indications for Use:

The HQS introducer (Model 2064-HQS) is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113849